

## REMARKS

35 USC § 103(a) Rejections – Obviousness

Claim 1 is now cancelled, making the obviousness rejections based on Tsujita et al. in light of Olukotun et al. in further view of Haytko et al. moot. Moreover, new claim 18, drawn to a “composition … having a purity of at least 99.7%... *comprising* pravastatin sodium salt … wherein the total level of impurity includes a reduced level of at least one impurity selected from the group consisting of: ....." with the specific impurities delineated, would not have been obvious by one of ordinary skill in the art based on Tsujita combined with Olukotun and Haytko because none of these reference provides any teaching relative to a composition comprising pravastatin sodium salt having a reduced level of at least one of these specific impurities, or how one could make such a purified HMG-CoA reductase inhibitor comprising pravastatin sodium salt with these particular impurities reduced.

Claim Objections

In response to the Examiner's comments that claims 13-17 would be allowable, if rewritten in independent form, Applicants have done as suggested. Therefore, claim 13 contains the limitations of previous claim 1, and as such, Applicants respectfully submit, is novel and non-obvious. Applicants therefore request withdrawal of the objections to claims 13-17.

Support for the Claim Amendments

Support for amended claim 13 is found in original claims 1 and 12; the application on p. 9, middle two paragraphs; p. 10 through p. 16; pp. 19-22, examples 1-4 and Table 1; and on pp. 26-27 in Example 15.

Support for new claim is found in original claims 1 and 6; the application on p. 7, lines 15-16 ("Within the scope of this invention the term "composition" shall mean a composition *comprised* of an HMG-CoA reductase inhibitor and of the impurities that are present in it"); and p. 8, lines 9-12 ("In the preferred embodiment of this invention fractions are obtained containing a composition of the HMG-CoA reductase inhibitor or a commercial scale composition of the HMG-CoA reductase inhibitor *comprising* the HMG-CoA reductase inhibitor and specific, reduced levels of impurities that are present in the said composition.") – emphasis added.

**CONCLUSION**

Applicants have amended claim 13, added new claims 18-22, and cancelled claim 1.

Claims 2-12 were previously cancelled in the July 16, 2005 Response to the restriction requirement of May 16, 2005. Applicants believe the application is now in condition for allowance and herewith request issuance of a notice of allowance.

Applicants believe that no extension of time is required for the submission of this response. However, this conditional petition is being made to provide for the possibility that the Applicants have inadvertently overlooked the need for an extension of time. If any fees are required for the timely consideration of this application, please charge deposit account number 19-4972.

Respectfully submitted,

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